

Patent
09/785,243REMARKS

Claims 7 and 10 are now pending. Claim 7 is independent. Claims 1, 6 and 8-10 have been cancelled.

Section 112, first paragraph rejection

Claims 10-11 were rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement and, specifically, states that "the specification does not adequately disclose a blood flow passageway through the partial helical shape as recited in the claims".

Applicants respectfully traverse the Section 112 rejection as to remaining dependent Claim 11. Specifically, Applicants submit that the subject matter of Claim 11 is supported by the disclosure of the application as filed. As noted in MPEP 2163.02, "an objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed'...an Applicant must convey with reasonable clarity to those skilled in the art that...he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed". This section continues, "the subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement".

Applicants respectfully direct the Examiner at least to Figures 2 and 6, and to page 11, lines 9-12 and page 12, lines 16-21, which are believed to provide the requisite written description to support Claim 11 and to satisfy the requirements of Section 112, first paragraph. Reconsideration and withdrawal of the Section 112 paragraph rejection are respectfully requested.

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Claims 1 and 6-11 were rejected under 35 USC 103(a) as being unpatentable over US Patent 6,033,383 (Ginsburg '383) in view of US Patent 5,624,392 (Saab) and US Patent 5,899,899 (Arless et al.).

Specifically, the rejection takes the position that "Ginsburg teaches all of the limitations of the claims" except (1) *returning fluid to a chiller*; (2) *providing a coaxial catheter*; (3) *insulating the supply lumen*; (4) *the heat transfer element being metallic*; and (5) *the heat transfer element being helical*.

The Action then relies upon Saab as teaching "a coaxial structure", providing "a chiller that recycles spent heat transfer fluid" and "to insulate the supply lumen to prevent cooling of tissue not intended for treatment located in close proximity to the device".

Finally, the Action relies upon Arless as teaching "a metallic heat transfer element" and a "helical heat transfer element".

The Action concludes that "it would be obvious...to combine the alleged teachings of Arless and Saab with the alleged teachings of Ginsburg to "provide a means of differential heating, to reduce the amount of fluid used by recycling fluid and to prevent thermal treatment of tissue not intended for treatment" and to "enhance heat transfer capabilities".

The outstanding rejection, as applied to remaining Claims 7 and 10, is respectfully traversed and reconsideration is requested.

Claim 7 is directed to a cooling apparatus that includes a circulating unit adapted for chilling and circulating a fluid, a flexible elongated catheter and a flexible tubular outer catheter body on the catheter. A flexible, insulated, supply tube is located within the outer catheter body, a proximal end of a central lumen of the supply tube being connected in fluid flow communication with an outlet of the circulating unit. A return lumen is located within the outer catheter body, and substantially surrounds the fluid supply tube, a proximal end of the return lumen being connected in fluid flow communication with an inlet of the circulating unit. A flexible heat transfer element is

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mounted to a distal end of the outer catheter body and has a partially helical shape to increase the surface area available for heat transfer. The fluid supply tube comprises a wall having insulating properties to reduce heat transfer from said return lumen to said central lumen of said fluid supply tube.

Ginsburg is directed to a temperature regulating catheter in which a "liquid medium is introduced into a lumen...[and is] altered while passing through the temperature altering region" (see Abstract) so that it may be "delivered to the target location while the fluid is within the patient" (col. 1, lines 9-11). As acknowledged in the Action, Ginsburg fails to teach or suggest (1) *providing a coaxial catheter*, and (2) *insulating the supply lumen*.

The Action relies upon Saab as providing a teaching of each of these elements. However, Applicants again respectfully submit that Saab does *not teach or suggest* Applicants' claimed "return lumen...substantially surrounding a fluid supply tube....wherinc said fluid supply tube comprises a wall having insulating properties to reduce heat transfer from said return lumen to said central lumen of said fluid supply tube".

Rather, the specific section of Saab noted in the Action, col. 11, lines 27-34, describe that "multiple lumens inside catheter tube 12 could be used to circulate a cryogenic fluid while sleeves 14 and 20 contained a heating fluid to insulate adjacent tissue along the length of the catheter except for the distal end beyond the end of sleeve 20". The Office Action even states only that Saab discloses "to insulate the supply lumen to prevent cooling of tissue not intended for treatment in close proximity to the device" (emphasis added).

The cited section of Saab relies upon a *heating fluid to insulate "adjacent tissue along the length of the catheter except for the distal end beyond the end of sleeve 20"*, and does *not* provide a teaching, or even a suggestion, of Applicants claimed fluid supply tube comprising a "wall", "having insulating properties", *to reduce heat transfer from said return lumen to said central lumen of said fluid supply tube*.

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Again, the structure recited in independent Claim 7 acts to "reduce heat transfer from the return lumen (that substantially surrounds the fluid supply tube) to the central lumen of said fluid supply tube" – this element is not taught or suggested by Saab's alleged teaching of "preventing cooling of tissue in close proximity to the device" by having "sleeves 14 and 20 contain a heating fluid".

The Ginsburg and Saab references plainly fail to suggest the claimed combination. Applicants therefore respectfully submit that independent Claim 7 is patentable over any combination of teachings of Ginsburg and Saab, and the rejection should be withdrawn.

Dependent Claim 11 is believed to be clearly patentable for all of the reasons indicated above with respect to Claim 7, from which it depends, and even further distinguishes over the cited references by reciting additional limitations.

Since the Applicants have fully responded to each rejection set out in the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Amendment After Final Rejection or of the application at

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large, request is made that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,


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I hereby certify that this document and any document referenced herein has been transmitted via facsimile to the US Patent and Trademark Office at (703) 872-9303 on September 18, 2003.

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